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SCIENCE MEDICINES HEALTH

Update on digitalization: eAF & IRIS Focus

11th meeting of the Industry Stakeholder Platform on the operation of the centralised procedure for human medicines
24 November 2023

Presented by Francisco Penaranda, Kristiina Puusaari

Overview of key concepts: PLM, eAF, RPM

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PLM Value Stream

- **Product Lifecycle Management (PLM)** is one of three EMA value streams covering the product lifecycle.
- It aims to **digitally transform and optimise regulatory procedure management (RPM),** as well as data submission and reuse, throughout the product lifecycle.
- This will be achieved by **delivering digital solutions** such as RPM on IRIS and web-based electronic Application Forms..

Electronic Application Forms

The **web-based electronic Application Form (eAF)** will replace current PDF-based electronic application form and be hosted on the PLM Portal

The new eAFs comply with the **ISO Identification of Medicinal Products (IDMP)** standard for human in accordance with Commission Implementing Regulation (EU) No 520/2012 (art. 25 and 26)

Regulatory Procedure Management

End-to-end Regulatory Procedure Management includes the **core procedure** and **all processes that enable it** (e.g., fees management, integrated access management, committees' meetings)

The aim is to deliver **optimised, sustainable and more digitally enabled** human and veterinary lifecycle procedures.

Save the date!

Join the **PLM VS Deep-Dive Webinar** (30 November 14:00 – 16:00) on Webex – *registration open*

Full overview of PLM VS products

Product Lifecycle Management Value Stream | Products' Delivery

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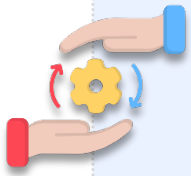
Product Lifecycle Management Value Stream

PLM Value Stream Platforms & Related Products

PLM Portal	**Electronic Application Forms (eAF)**	Web-based electronic application forms replacing PDF forms
	Electronic Product Information (ePI)	Electronic product information available online
	Product Data Management UI	Interface addressing latest regulatory data requirements and enables transparent master data exchange
Veterinary UPD	**Union Product Database (UPD)**	Single source of information on all authorised veterinary medicines
Product Data Mgmt Services	**Product Management Service (PMS)**	The product management service providing standardised and structured product master data for human medicinal products
PLM Regulatory Procedure Management (IRIS)	**PLM Regulatory Proc. Mgmt.**	Regulatory procedure management transition to a single platform
	Expert Panels for Med. Devices (EXPAMED)	Single system for information, communication, and management of medical device evaluation procedures
European Medicines Web Portal	**Veterinary Medicines Web Portal**	Portal providing trusted public information on all veterinary medicinal products marketed in the EU/ EEA
	Human Medicines Web Portal	Portal providing trusted public information on all human medicinal products marketed in the EU/ EEA
Electronic Submission and review tools	**Submission Review Tool & Common Repository**	Updated review tool for industry submissions

RPM for PLM Updates

Key updates on Regulatory Procedures for PLM transition to IRIS



- 1st roll-out of variations, art 61.3 notifications, Marketing Authorisation Transfers on IRIS will be in Q1 2024
- Preceding the roll-out, a User Acceptance Testing with Industry SMEs will take place at the end of November 2023

These timeframe adjustments are made to enhance preparation for these crucial milestones and guarantee a seamless transition to the new system

Regulatory Procedure Management for PLM Timeline (October 2023)

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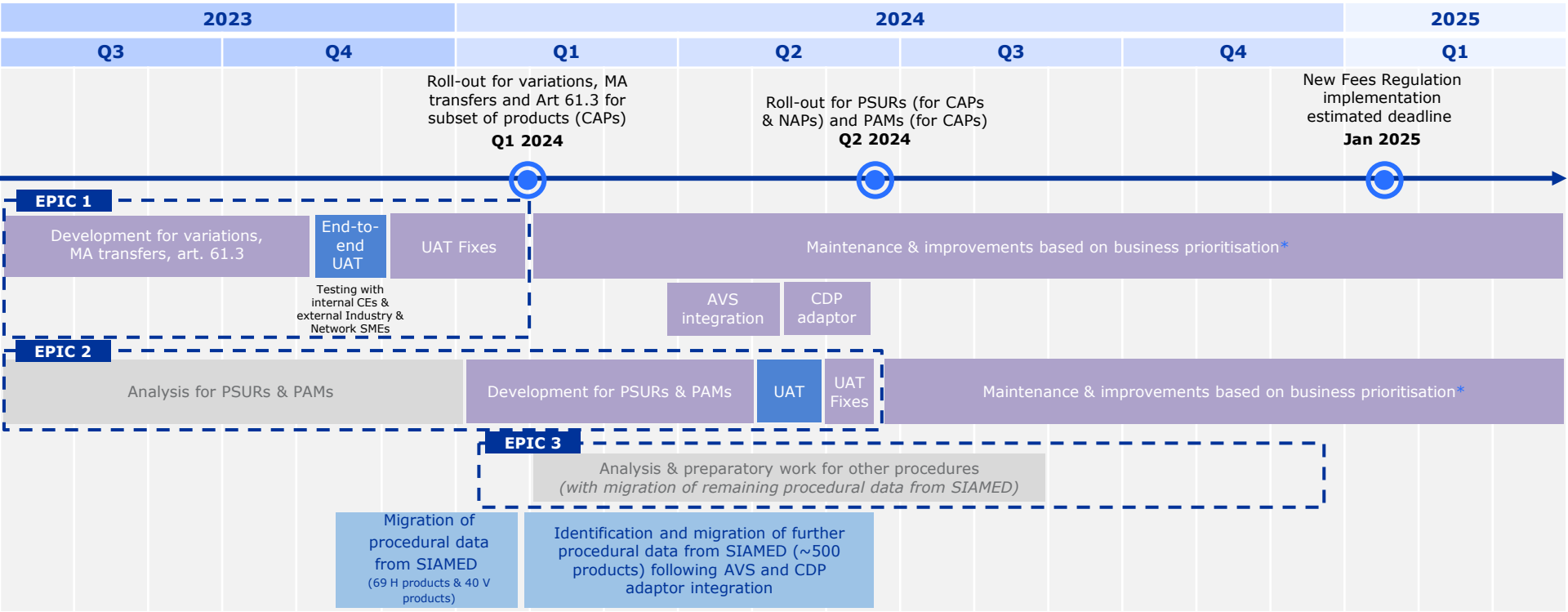

Please note the ongoing development of RPM will happen epic by epic , with incremental improvements across the entire regulatory procedure management landscape.

Acronyms

AVS: Assisted Validation System
CAPs: Centrally Authorised Products
CDP: Clinical Data Publication adaptor
CEs: Change Enablers
MA: Marketing Authorisation
NAPs: Nationally Authorised Products
PAMs: Post-Authorisation Measures
PSURs: Periodic Safety Update Reports
SMEs: Subject Matter Experts
UAT: User Acceptance Testing

Legend

Milestone
Development activities
Migration activities
UAT activities
Analysis & preparatory activities

1st roll-out products' selection

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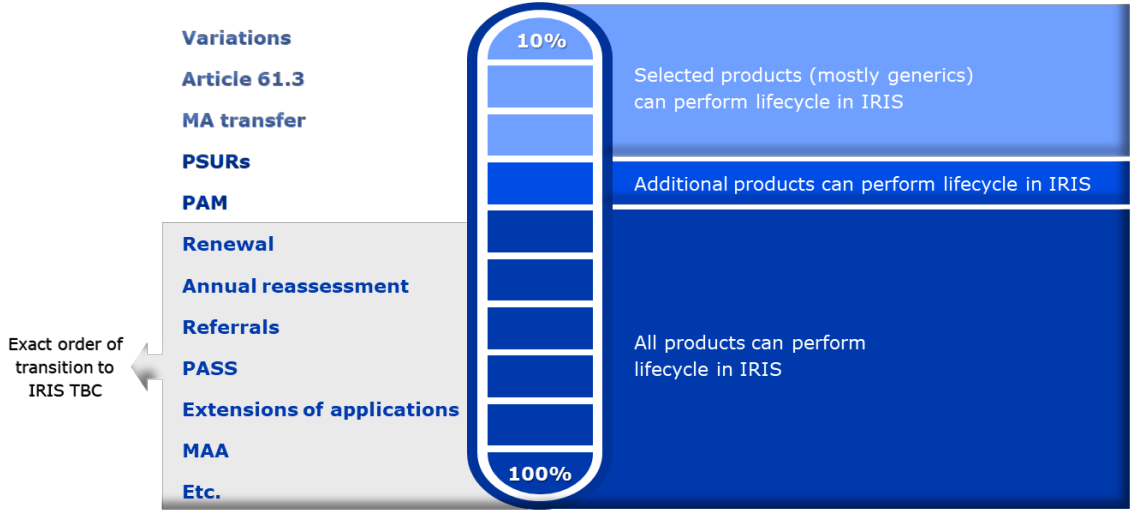
For the first transition to IRIS, the RPM team has selected a **subset of human and veterinary products (mainly generics) allowing full transition of the PLM into IRIS**.

Steps taken to assure optimal subset of products for November roll-out

- Agreement with EMA impacted teams' management;
- Inform rapporteurs on the selected products for roll-out;
- Request of submission plans from MAHs with selected products by mid-September 2023;
- Review of MAHs submission plans;
- Confirmation of product selection for 1st roll-out to MAHs and rapporteurs

The more regulatory procedures are onboarded to IRIS, the more products can perform product lifecycle in IRIS



*In total, this has led to the selection of **69 human products** (generics) **40 veterinary products** (mainly generics).*

Key impacts for MAHs after the 1st roll-out

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AS-IS	TO-BE
Submission process through **eCTD and Gateway**	Submission process is **unchanged**
After receipt of a technically valid submissions, EMA creates a **case (procedure) in SIAMED**	After receipt of a technically valid submissions, EMA will create a **case in IRIS**
The *MAH contact receives information* about the case **via email/ Eudralink**	The *MAH contact (*default, user stated in MAA eAF section 2.4.3*) becomes case manager and contact, has access* to the case in the **IRIS Industry Portal** and will be able to **follow the case until closure**
Case contact change requires **contacting EMA** and submitting letter of authorisation	Case managers **can change** the submission contacts and add users as managers/contributors to access/ modify submission
During the procedure the *document exchanges* (outside eCTD/VNeeS) will take place **via Eudralink**	During the procedure the *document exchanges* (outside eCTD/VNeeS) will take place via **IRIS portal** (no Eudralinks/email attachments)
EMA outcomes will be sent to the MAH **via Eudralink**	*EMA outcomes* will be **visible in the IRIS Industry Portal** and documents are available for Industry to download directly

Cooperation with Industry Subject Matter Experts

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Selected based on their expertise, appointed Industry SMEs **cooperate with RPM for PLM product team**, providing **advice and recommendations** as well as occasional hands-on work for the benefit of consistent process enhancement for RPM for PLM.

Participation to:

- Bi-weekly meetings with product team
- Preparatory UAT (June 2023)
- End-to-end UAT (end of November 2023)

Industry Subject Matter Experts

Human Domain:

- Gunther Pfeifer (AESGP)
- Gemma Swaisland-Kemp (Europa Bio)
- Laura Casals Comellas (Medicines for Europe)
- Tena Havrda (Medicines for Europe)

Veterinary Domain:

- Patrizia Oelker (AnimalhealthEurope)
- Simon Turek (AnimalhealthEurope)
- Eusebio Uruburu Alonso (AnimalhealthEurope)

Next Steps

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Next steps before 1st roll-out start

- **Update** on 1st roll-out date (Dec 2023)
- Public **System Demo** (Dec 2023)
- Publication of **user guide** (Dec 2023)
- **Training activities** for MAHs with selected products for roll-out (Q1 2023)

eAF Updates

Human Variations eAF – upcoming key activities and milestones

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Known & target timeframe

November 2022 | **December 2023** | **Q1 2024**

Incremental release of functionalities required for mandatory use

*CAPs migrated from SIAMED not following ISO IDMP structure. For this reason, they have undergone a further step in the data migration to PMS in addition to the match and merge protocol.

Note: CAPs and NAPs data in PMS is sourced from EMA's internal database (SIAMED) and XEVMPD

Acronyms

CAPs: Centrally Authorised Products

NAPs: Nationally Authorised Products

XEVMPD: eXtended EudraVigilance Medicinal Product Dictionary

Legend

Key step/ Milestone

Dev activities for Human variations eAF

Recurring activity

Timeframes

Key enablers for split CAPs/NAPs release on eAF & ongoing work

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Key enablers for split CAPs and NAPs release

1. **Bug fixing** across PMS & IRIS products
2. **Release of all products from PMS** to the IRIS UAT environment
3. **Successful execution** of internal **UATs** to confirm bug fixing across PMS & IRIS products

Ongoing work on eAF features

- **Name translations** to be implemented *ahead of NAPs release*
- Kindly be aware that **additional features** pertaining to the use of the forms for NAPs will be **introduced at a later stage** (*after NAPs release*).

  Initially, there will be some limitations due to unavailable features (e.g., the form will not be available for homeopathic products), but it will *still be valuable for individuals to use the eAF for NAPs to familiarise with the form*.

Next steps

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Before NAPs release

- **Update** on development progress (Dec 2023)
- Public **System Demo** (Dec 2023)

After NAPs release

- **Release** of features and functionalities **required for mandatory use**
- **eAF User Acceptance Testing announcement** (2 months in advance)
- **eAF UAT** (2-week duration) of the version of the form ready for transition
- **Confirmation** of transition start (2 months in advance)
- **Transition period** (6 months)
- Start of **mandatory use**

Q&A